Description

Sternum reinforcing device to be used after a sternotomy or a sternal fracture

Technical Field

This invention relates to a sternum reinforcing device to be used after a sternotomy or a sternal fracture.

Background Art

The median sternotomy is a very usual operation in the field of heart surgery. The sternum or its portion of a patient is sawn by a saw or other cutting means. When all the sternum is severed in two, its sternal halves are spread apart laterally the one from the other so that mediastinum structures can be exposed. As a result, a large aperture is formed in the thoracic cavity, which permits an optimal surgical access to the heart and great vessels and also is well tolerated by the patient.

Once the operation is completed, the two sternal halves are rejoined. Traditionally, several means, such as Mersilene fibres, steel wires, metal and plastic bands, nitinol clamps, etc. are used for a sternal closure in order to assure the sternal stability and the recovery of the patient. The most usual current method of doing this is to use steel wires around the sternum passing through intercostal spaces.

However, both the medial sternotomy and the current methods are not free of complications. The complications of the sternal wound, usually due to the sternum instability, range from prolonged thoracic pains, which cause inconveniences and related respiratory disorders up to the dehiscence of the wound at the risk of infections and mediastinitis.

US Patent 4,583,541 already provides a sternal stabilizer for holding a severed

sternum closed. Such a stabilizer consists essentially of a single strap-like member, which is adapted to overlie, in longitudinal and centrally relation, the anterior surface of a divided sternum of a patient. Such a strap-like member is provided with a plurality of pairs of through holes. A plurality of wires extend from the sternum posterior surface through holes formed in the sternum concentrically to the strap-like member through holes and are tied or twisted together within a central groove. The above patent would intend to overcome problems occurring with the complications seen after median sternotomies. These problems range from wires breaking, wires protruding through the skin e.g. upon a patient's slimming, separation of the sternal halves, failure of the sternum to heal, infections and loose or unstable sternal halves.

Differently from the above patent that intends to protect a sternal stabilizer which appears to be limited in its function due to the need of fitting together holes in the sternum and those in the strap-like member, this invention aims to create a partial or full reinforcement for one sternal half or both, considering that sternotomy operations are carried out more often in elderly patients, whose skeletal system is losing more and more its strength in time.

Therefore, an object of the present invention is to manufacture a device adapt to be used in the sternal closure that provides a lateral reinforcement to the sternal halves as well as to both anterior and posterior portions of the sternum.

Another object of the invention is to perform a sternal closure similar to that could be made through a wire binding, without any risk of rubbing of the wire on the sternum which could generate subsequent lesions and consequent partial or complete fractures and wire loosening.

A further object of the invention is to permit a closure also in parts affected by partial or complete fractures of the sternum, which are subsequent to a primary operation.

Yet a further object of the invention is to allow the sternal halves be closed during an operation for sternal dehiscence particularly without being necessary to separate any adherence being formed in meanwhile, which would involve a high risk of damage to the heart and any bypasses and relevant ducts.

Yet another object of the invention is to reinforce sternums which can be closed again by traditional methods at the risk of complications, owing to ageing or degeneration processes, such as the osteoporosis process, on patients that are affected also by diabetes, respiratory insufficiency, or obesity, or that have been subjected to paramedian sternotomies.

Disclosure of the Invention

Therefore, the invention provides a sternum reinforcing device to be used after a sternotomy or a sternal fracture, characterised in that the device comprises at least an elongated modular member, which is designed to be located on a surface portion of an anterior edge of a sternum and provided with a first and a second connection parts, said first part of said elongated modular member being adapted to join with a second connection part of a preceding elongated modular member, said second part of said elongated modular member being adapted to join with a first part of a following elongated modular member; each elongated modular member being further provided with a projecting portion designed to be fitted in an intercostal space adjacent to the lateral edge of the sternum.

Brief Description of Drawings

The present invention will be described referring to two preferred embodiment thereof, with connection to the enclosed drawing, in which:

Figure 1 shows a plan view of a plate blank which is shaped to obtain a first

embodiment of the sternum reinforcing device according to the present invention;

Figure 2 shows in a perspective view the sternum reinforcing device in the form of an elongated member obtained by the plate blank in Figure 1;

Figure 3 shows in a perspective view a sternum reinforcing device having three elongated members as that one in Figura 2, which are mutually engaged consecutively;

Figure 4 shows a plan view of a plate blank which is shaped to obtain a second embodiment of the sternum reinforcing device according to the present invention;

Figure 5 shows in a perspective view the sternum reinforcing device in the form of an elongated member obtained by the plate blank in Figure 4;

Figure 6 shows an elevation side view of the sternum reinforcing device in Figure 5, being rotated 90 degrees in the drawing sheet;

Figure 7 shows a top plan view of the sternum reinforcing device in Figure 6;

Figure 8 shows an end plan view of the sternum reinforcing device in Figure 6;

Figure 9 shows a plan view of a retaining splint according to the present invention;

Figure 10 shows in a perspective view a sternum reinforcing device having three elongated members as that one in Figure 5, which are mutually consecutively engaged and further provided with a retaining splint (partially shown) as that one in Figure 9; and

Figure 11 shows in a diagrammatic perspective view reinforcing devices according to the present invention, which are bilaterally fitted in a sternum.

Description of preferred embodiments

With reference to the drawings, shown in the plan view of Figure 1 is a first embodiment of the device according to the present invention in a semifinished condition, i.e. in the form of a punched plate blank (totally lying in the plane of the drawing sheet). The reinforcing device can be manufactured from a sheet of

biocompatible material, e.g. stainless steel, being shaped by punching or other cutting process such as electrical discharge machining or laser cutting, etc. into a modular elongated member. Mechanical and technological characteristics of the material are selected in order to assure suitable mechanical working properties, usefulness and functionality to the device. Obviously, the reinforcing device can be obtained by machining as well as by casting, or from a not metallic material and by a different working method.

The elongated modular member 1 is shaped in a such way that a small body portion 4 is made in the form of a gusset in a intermediate position of the elongated modular member 1. The body portion 4 is contiguous to a central portion 5 of the modular member 1, a bending line l_4 being provided between them. Formed laterally to the body portion 4 are edges 2, 3 bordering on the body portion 4 along respective folding lines l_2, l_3, but being separated from the central portion 5.

The modular member 1 has connection parts in the form of arms 6, 7 being extended the one in one direction, the other in the opposite direction, with respect to the central portion 5. The arm 6, having a flat rectangular cross-sectioned profile, is slightly tapered toward its free end 8. The arm 7 is extended transversally by fins 9, 9, which can doubly bent by virtue of pairs of parallel bending lines $2l_9$, $2l_{10}$.

The punched plate blank in Figure 1 is shown erected, ready to be used, in the perspective view in Figure 2. In this figure the body portion 4 is shown is orthogonally bent downward, thus as if it penetrates the drawing sheet, and the side parallel edges 2 and 3 of the body portion 4 are bent substantially at right angle outwards to form an U-shaped cross-section adapted to retain clamping means (to be described below).

Fins 9, 9 are doubly bent to form a so called channel hollow profile cross-section. Fins 9, 9 are bent upwards (as shown in Figures 2 and 3) or downwards (as later shown in Figures 5, 6, 7, 8, 10, and 11) with respect to the drawing sheet and then in parallel to

the latter, by virtue of pairs of parallel bending lines $2l_9$, $2l_{10}$. It should be evident that the choice of bending the fins 9, 9 upwards or downwards in order to create a hollow cross-section, can be suggested by a more comfortable use in installing the device in the first case, and by a more finished front surface of the same device once it is in situ, in the second case, and by other remarks easy to understand.

In Figure 3 there is shown the sternum reinforcing device of the invention as a unit of three elongated modular members according to the first embodiment in their assembling step. Thus, this unit will be installed as shown in a diagrammatic perspective view in Figure 11. The elongated modular members are indicated generally as 1 and distinguished by an index in a plurality 1_1, 1_2, ..., 1_n, n being generally equal to 4 at the most.

As seen in Figure 3, the elongated modular members 1_1, 1_2, 1_3 are connected consecutively by means of prismatic sliding couplings, whereby the male arm 6 of the modular member 1_1 is fitted in the female arm 7 of the consecutive modular member 1_2, and the male arm 6 of the latter is fitted in the female arm of the consecutive modular member 1_3. The elongated modular members 1_1 and 1_2 fully interpenetrate, the end of the female part of the one abutting on the projecting edge 2 of the other. The member 1_3 is shown as spaced from the others.

The sizes of the body portion 4 are such that it can be fitted in the intercostal space of any patient. On the other hand, the longitudinal sizes of the arms 6, 7 and the amount of their mutual sliding are selected in such a way to allow the one elongated member and the consecutive one to be spaced so that they are adjusted to any rib width of a patient. In other words, a modular member can be spaced from the consecutive one in the measure required for fitting the body portion in the relevant intercostal space, without loosing their mutual contact.

With reference to Figure 4, therein a second embodiment of the modular device

according to the present invention, indicated as 10 as a whole, is shown by a plan view similar to that in Figure 1.

For clarity sake, in describing the second embodiment similar reference numerals and signs are used to indicate parts that are identical or similar to those of the first embodiment. The second embodiment differs from the first embodiment as the edges 2, 3 extend from the body portion 4 to form legs 20, 30.

The punched plate blank in Figure 4 is shown in its erected form, ready for its use, in the perspective view of Figure 5. Therein the body portion 4 is shown bent orthogonally downwards, thus as if it penetrates the drawing sheet, and the two lateral legs 20 and 30 are bent substantially 90 degrees outwards. As for the first embodiment, the fins 9, 9 are bent to form a channel-shaped cross-section. The counter-rotating arrows F indicate that the lateral legs 20, 30 can be bent in the opposite direction to abut themselves on the internal surface of the thorax in correspondence with the respective ribs in order to create a suitable clamping. Therefore, a material of which the reinforcing device is made has to be suitably bendable also only by hand.

The second embodiment of the invention is shown by three orthogonal views in Figures 6 to 8. It should be appreciated that Figure 7 is also a plan view of the first embodiment. In order to prevent a repetition, Figures 6 to 8 are not described in detail.

A plan view of a retaining splint 12 to be used in connection with the second embodiment of the invention is shown in Figure 9. The retaining splint 12 is provided with slots 13 so dimensioned that the legs 20, 30 can pass through them. In one side of the retaining splint 12, there are wire guiding notches 14.

In the installation, a plurality of elongated modular members 10_1, 10_2, ..., 10_n are connected together by fitting the male arm 6 of a modular member in the female arm 7 of a consecutive modular member, as already explained for the first embodiment.

When a sufficient number of elongated reinforcing members is reached, the installation in the thorax can be performed, by fitting male and female arms also not completely, in case, in order to respect the intercostal spaces. In Figure 10 there is shown how to fit legs 20, 30 of the retaining splint 12 in the direction of arrows G-G to create an internal greater clamping before rotating the same legs in the direction of arrows F-F.

As shown in Figure 11, two series of elongated reinforcing members are fitted from the front of the thorax, on anterior edge portions of a sternum that was subjected to a sternotomy or partial fracture. Figure 11 refers to the second embodiment, but it could refer also to the first one. If there are the legs 20, 30, once they are fitted, they are bent as indicated by the arrows F in opposite direction to be anchored in the internal part of the thorax. The legs 20, 30 can be bent after the retaining splint 12 has been fitted, which generates a better distribution of stresses in the thorax. At the end, the two series of reinforcing devices are locked by a wire 15 passing between the edges 2, 3 of each body portion 4. Although not shown in the drawings, the body portion 4 could be suitably bent to create a central guiding surface for the wire 14 already limited by the lateral edges 2, 3 bent outwards.

In such a way, the reinforcing device can be installed only where it is required. The tying wire is surrounded by the reinforcing device, and it will not imply the risk of sternal dehiscence due to loosening of wire or other complications, such as the rubbing of the sternal wires in the normal respiratory movements of the thorax.

By virtue of the particular reinforcing device according to the invention, the sternum can be closed, besides by traditional wires, also by tapes and bands, which are suitably received between the edges 2, 3 of the body portion 4.

The elongated members can be used in a required number, and form together a single reinforcing group. Although in Figure 11, the elongated members are positioned both

on one side and the other of the sternum in order to fully reinforce it, a less number of them can be used to reinforce only or partially a sternal half or both.

The use of the reinforcing devices can be avoided in those cases in which the sternum is in such good conditions that they are not required.

The persons skilled in the field will understand that modifications and variations can be made to the device as above set forth. Although in the embodiments described and illustrated the connection parts forms prismatic couplings, they could create different forms of coupling, either movable or adjustable, between an elongated member and another one. For example, the coupling of at least two pins, projecting upwards from an elongated member and being movable in a slot of a consecutive member could be chosen. Also the shapes of the parts can be different. For example, the body portion could be arranged not angularly to the remaining elongated member, but with some convexity fitting the lateral configuration of the sternum. It is intended that all modifications, if any, to the device, do not take away the device from the scope of the invention as set forth in the enclosed claims.